SM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,686	01/11/2002	Zheng-Zheng Zhou	065883.0106	8199

7590 03/22/2004

Roger Fulghum
Baker Botts L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, TX 77002-4995

EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,686	ZHOU ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

SCOPE OF ENABLEMENT REJECTION

Claims 1 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lattice constant calculating practice inclusive of at least some measurements of micro-array element dimension(s), does not reasonably provide enablement for generic calculating without some micro-array measurement data input. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

The calculating step in claim 1, line 3, is broad and generic and lacks any limitation which connects the calculation of a lattice constant to elements of the micro-array cited in the claim. It is acknowledged that the calculating step in claim 1 is directed to the calculation of a lattice constant of "the micro-array" but without starting with at least some requirement that the lattice constant be derived from a dimension and/or set of locations of elements of said micro-array. For example, in claim 2 at least a distance is measured between peaks of a periodogram which is apparently a measurement of element locations on said micro-array. No such limitation is present in claim 1. Thus, the calculation of a micro-array lattice constant is complete and undue experimentation as in claim 1 without some measurement data to guide the calculation. Claims which depend directly or indirectly from claim 1 which do not contain at least some element spacing or micro-array measurement(s) are also rejected hereinunder due to their dependence.

VAGUENESS AND INDEFINITENESS

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 3, cites the calculation of a lattice constant but confusingly does not related this to any other practice in the claim. For example, the grid which is aligned in line 4 of claim 1 may be assumed to be characterized by the lattice constant calculated in line 3, but this is not stated as such in the claim. An assumption of such a connection between the lattice constant of line 3 and the grid of line 4 of claim 1 is reasonably only

an assumption and not clear and concise as required by 35 U.S.C. § 112, second paragraph. Claims which depend from claim 1 directly or indirectly are also vague and indefinite due to their dependence.

Similarly, lines 5-6 of claim 1 cite the "performing" of "a local spatial adjustment to each element of the micro-array" which is again apparently assumed to be applied to the grid alignment in line 4, but not clearly and concisely stated in the claim or in claims dependent from claim 1.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10, and 14 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Yu et al. (P/N 5,086,477).

The instant claims cite the identification of elements of a micro-array but neither the claims nor the specification limits what is meant by the phrase "micro-array". It is acknowledged that nucleic acid micro-arrays which are generally utilized for hybridization assays to nucleic acid probes on said micro-array is exemplified at numerous citations in the instant disclosure as filed, but, again without any concise

limitation of what is meant by the phrase "micro-array" either therein or in the instant claims. It is also noted that there is no instant definition of what size is meant for "micro" as a characterization of a micro-array or a term utilized equivalently in the art which is simply referred to as an array. Yu et al. is directed to imaging integrated circuits as summarized in the abstract. Without a limiting definition for micro-array such arrays of circuit elements which are positioned on a semiconductor chip is reasonably included in micro-array practice. The specific citation of "array" for such a semiconductor chip is set forth in the reference in the bridging sentence between columns 4 and 5. Features or elements are imaged (local spatial adjustment as in instant claim 1, line 5) on the array of the reference as cited in column 2, lines 25-43, as well as dimensions thereof as disclosed in column 3, lines 28-39. The elements on an array are delineated regarding boundaries as disclosed in column 6, lines 33-52, as also required in the last line of instant claim 1. A grid is set up to align to elements on an array as disclosed in the reference in column 5, lines 53-62, inclusive of grid spacing which is reasonably the result of a calculation of a lattice constant for the array as also required in instant claim 1, lines 3 and 4. Local spatial adjustment to elements of an array are also disclosed in the reference in column 9, lines 5-13, and related element imaging disclosure thereafter as required in instant claims 1 and 10. Thus, the limitations of the above listed instant claims are anticipated by Yu et al. Yu et al. additionally discloses the matching of cell structures or elements on an array to a reference library of elements as cited in column 12, line 62, through column 13, line 18, which thus are deemed to be reference

constraining shape masking as required in instant claim 14 over the limitations already cited above in the reference.

Claims 1, 5-7, 10, and 14 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Gaidoukevitch et al. (P/N 6,498,863).

The abstract of the reference directs the invention therein disclosed to analyzing an image of an array with grid practice. Specific DNA array (or micro-array as instantly claimed) practice imaging is further disclosed in column 1, lines 12-25, as the subject matter of the reference. The SUMMARY OF THE INVENTION section in columns 3-4 of the reference also summarizes the formation and alignment of a grid overlay over an array with calculating angles between the rows and columns thereon as well as the overall array dimensions which either of which define the lattice constant for the array being imaged as also instantly claimed in claim 1, lines 3-4. Local spatial adjustments of elements and their boundary delineations of the array as in instant claim 1, lines 5-7, and instant claims 10 and 14, is described in column 4, lines 23-34. The calculation of row and column angles and positions as summarized in columns 3-4 of the reference is reasonably deemed to anticipate the auto-correlation calculations of x and y direction lattice constants as in instant claims 5-7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (P/N 5,086,477); taken in view of Pirrung et al. (P/N 5,143,854).

The disclosure of Yu et al. has been summarized above, however, it may be interpreted as requiring further motivation to apply such semiconductor technology to element recognition on micro-arrays as utilized in embodiments of the instant invention on which nucleic acid probes are immobilized. Pirrung et al. is cited herein to supply motivation to connect semiconductor technology to nucleic acid micro-array technology due to the utilization of semiconductor technology with nucleic acid probe array or microarray technology as this is cited in Pirrung et al. in column 13, lines 36-43, motivated therein for all purposes.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to apply the imaging practices of Yu et al. to nucleic acid micro-array or array practice as motivated in Pirrung et al. for all purposes thus resulting in the micro-array methodology practice of the instant claims as listed above.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

March 17, 2004

Ardin H. Marschel 3/17/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER